

REMARKS

Claims 1-8, 14, 16-63, 69 and 71-80 are pending in this application. Claims 30-55 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-8, 14, 16-23, 25-29, 56-63, 69 and 71-79 were rejected under 35 U.S.C. § 112, first paragraph. Claims 20 and 26 were rejected under 35 U.S.C. § 102(b). Claims 1-29 and 56-79 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

By this amendment, claims 1, 20 and 56 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments can be found, *inter alia*, throughout the specification, for example, at page 30, lines 27-30. As discussed herein, the amendment is made to better place the application in condition for allowance by including limitations which the Examiner indicates support the written description requirement. Thus, Applicants respectfully submit that the amendment is does not raise new issues and respectfully request entry of this amendment.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants thank the Examiner for indicating that claim 24 is free of the cited art.

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-8, 14, 16-23, 25-29, 56-63, 69 and 71-80 were rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

The polynucleotide component of the claimed IMP/MC complex is the focus of this written description rejection. The Examiner asserts that the specification and claims “do not indicate what distinguishing attributes are concisely shared by the members of the genus” and that “the disclosure fails to describe the common attributes or characteristics that identify members of the genus.” The Examiner also asserts that “[g]iven that Applicants claims do not recite the length of the ISS sequence, or the amount of space permitted between the 5’ C and the G’ 3, each and every DNA encoding gene in the entire genome will be encompassed by this claim. Clearly, one of skill would still not be able to identify members of the genus, as no members appear to be excluded.” The Examiner concludes that “[o]ne of skill in the art would simply be unable to identify the members of the genus based upon this bare bones structural requirement.” Office Action, pages 3-4. Applicants respectfully disagree with this description of the claimed invention and with these assertions.

The claimed invention is directed to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a nonbiodegradable microcarrier. In claim 20, the polynucleotide in the complex is 7 nucleotides in total length, including the dinucleotide sequence 5’-CG-3’. As amended herein, in claims 1 and 56, the polynucleotide is less than about 200 nucleotides in length and comprises a 7 nucleotide sequence selected from the group

consisting of 5'-TCGAAAA-3', 5'-TCGCCCC-3', 5'-TCGGGGG-3', 5'-TCGTTTT-3' and 5'-TCGTCGX₁-3', wherein X₁ is a nucleotide.

The polynucleotide in the complex of claim 20 is 7 nucleotides in length and includes the dinucleotide 5'-CG-3'. Thus, this structural description of the polynucleotide in this claimed complex identifies a discrete number of members of the claimed genus and the specification describes approximately 100 of its members on pages 22-25.

The length of the polynucleotide in the complex of claims 1 and 56 is between 7 and about 200 nucleotides in length. This polynucleotide also comprises an ISS sequence selected from the group of five 7-mers recited in the claims. Thus, the genus of polynucleotides recited in these claims is far more limited than that described in the Office Action and Applicants respectfully submit that a skilled artisan would recognize possession of that genus from the specification's disclosure.

The specification provides a description of sufficient, relevant, identifying characteristics of the claimed polynucleotides that one skilled in the art would recognize that the inventor had possession of the claimed invention when the application was filed. Applicants respectfully submit that the specification in combination with that known in the art adequately describes possession of the claimed genus to one skilled in the art. See *Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, USPQ 65 USPQ2d 1385 (Fed. Cir. 2003); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). Thus, the pending claims are fully described in the specification as filed and Applicants respectfully submit that the written description requirement has been met.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. §102(b)

Claims 20 and 26 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Uhlen (U.S. Pat. No. 5,629,158). Applicants respectfully traverse this rejection.

Claim 20 is directed to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a nonbiodegradable microcarrier. The polynucleotide in the claimed complex is 7 nucleotides in total length, including the dinucleotide sequence 5'-CG-3'. Claim 26 is directed to the complex of claim 20 further comprising an antigen.

In this rejection, the Examiner states that the “claims recite “comprising... 7 nucleotides in length.” This open ended language allows for polynucleotides of 7 nucleotides up to and including positive infinity.” Office Action, page 7. Applicants respectfully traverse this characterization of claim 20. Claim 20 clearly states that the polynucleotide of the complex is 7 nucleotides in length. The claim uses the term “comprising” in relation to the complex comprising a polynucleotide and a nonbiodegradable microcarrier. Thus, the claimed composition has been mischaracterized by the Office.

The Examiner cites SEQ ID NOs: 2, 4 and 14 of Uhlen as examples of the anticipatory disclosure of Uhlen (Office Action, page 7). Applicants respectfully point out, however, that SEQ ID NOs: 2, 4 and 14 of Uhlen are 36, 19 and 29 nucleotides in length, respectively. The Examiner also acknowledges “that the sequence disclosed by Uhlen is longer than 7 nucleotides” (Office Action, page 7).

For a claim to be anticipated by a reference, the reference must teach each and every element of the claim. Uhlen does not teach an IMP/MC complex, where the microcarrier is a non-

biodegradable microcarrier and where the polynucleotide is 7 nucleotides in length. Thus, Applicants respectfully submit that Uhlen does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections Under Obviousness-Type Double Patenting

Claims 1-29 and 56-79 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-11 and 56-66 of copending U.S. Application No. 09/802,376 and over claims 1-11 and 56-66 of application No. 09/802,375. Although this rejection includes claims 9-13, 15, 64-68 and 70, Applicants respectfully point out that these claims have been canceled. The Examiner states that this is a provisional rejection because the conflicting claims have not yet been patented. Accordingly, Applicants will respectfully defer a response to this rejection until patentable subject matter has been identified in one of the applications.

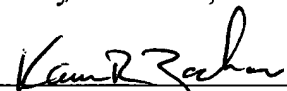
CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 377882001720. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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